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ALSTON & BIRD LLP BANK OF AMERICA PLAZA 101 SOUTH TRYON STREET, SUITE 4000 CHARLOTTE, NC 28280-4000			EXAMINER ANDERSON, HEATHER L	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/539,427

Applicant(s)

PALPU ET AL.

Examiner

Heather L. Anderson

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-893)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of the species *Boerhaavia diffusa* and *Vitis vinifera* within species A and *Saccharomyces* within species B in the reply filed on 16 November 2007 is acknowledged.

Claims 1-16 are presented for examination on the merits.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

Claim Objections

Claims 4, 9 and 15 are objected to because of the following informalities: typographical errors resulting in the misspellings of *Saccharomyces* and *Woodfordia fruticosa*. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antioxidant herbal soft drink comprising *Sida* spp., *Boerhaavia diffusa*, *Vitis vinifera*, *Tinospora cordifolia*, *Withania somnifera*, jaggery, *Woodfordia fruticosa* as the fermenting agent and carbonated water and a method of making thereof, does not reasonably provide enablement for an herbal soft drink having antioxidant properties as well as hepatoprotective, cardio-tonic, diuretic, digestive, cholerectic, nervine relaxant and immuno-enhancing properties comprising a concentrated herbal extract obtained from a mixture of only two or four herbs selected from the group consisting of *Sida* spp., *Boerhaavia diffusa*, *Vitis vinifera*, *Tinospora cordifolia* and *Withania somnifera*, along with jaggery, any and all fermenting agents and carbonated water and a method of making thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 ¶ 1, the courts have put forth a series of factors. See, In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988); and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* While it is not essential

Art Unit: 1655

that every factor be examined in detail, those factors deemed most relevant should be considered.

Applicant has reasonably disclosed/demonstrated that an herbal soft drink comprising *Sida* sps., *Boerhaavia diffusa*, *Vitis vinifera*, *Tinospora cordifolia*, *Withania somnifera*, jaggery, a fermenting agent and carbonated water that is made by the instantly claimed method would have antioxidant properties. However, the claims encompass any and all herbal soft drinks that could be made from any combination of two or more herbs selected from *Sida* sps., *Boerhaavia diffusa*, *Vitis vinifera*, *Tinospora cordifolia* and *Withania somnifera* so as to provide not only an antioxidant functional effect, but also hepatoprotective, cardio-tonic, diuretic, digestive, cholorectic, nervine relaxant and immuno-enhancing effects, which is clearly beyond the scope of the instantly claimed/disclosed invention.

The experimentation disclosed in the specification is directed towards demonstrating only the antioxidant properties of the herbal soft drink comprising all five herbs. All of the working examples described have these same ingredients, just in slightly different percentages. There is no experimentation conducted involving the other seven properties besides antioxidant properties, as well as no experimentation conducted with various combinations of two or more of these five herbs, in particular of the elected species. Furthermore, only very limited additional guidance is provided by the specification with regard to the details for the method for making this herbal soft drink beyond what is given in the claims. For example, where the herbs decocted (boiled), such as in the making of an arishta, or were they merely extracted via a cold

Art Unit: 1655

infusion technique as implied by the claims, such as in the making of an asava?

Additionally, which of the working examples was used in the experimentation (i.e., what is C1)? How are the solutions concentrated?

The nature of this invention is a combination of the carbonation of a soft drink with the making of a traditional herbal wine of India. Each of the various herbs used in this drink and process all has their own chemical and physical properties, and each of the combined processes is well-known to one of skill in the art of herbal drinks, as demonstrated by the specification (see, i.e., page 1, lines 14-19). The art of herbal drinks is unpredictable due to the fact that the properties of each product made would vary based on the different herbs used and the processing of the herbs, so any of the various combinations of two or more of the five herbs listed would each have different properties. The instant claims for the invention cover a very wide variety of different physical ailments and conditions as well as quite a large number of combinations of two or more herbs selected from the five listed.

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to make and/or use the instantly claimed product, as well as the instantly claimed method of making thereof, other than via using a combination of all five of the instantly claimed herbs (as instantly demonstrated) in the recited ratios, for the reasons discussed above

All other claims depend directly or indirectly from rejected claims and are therefore, also rejected under 35 U.S.C. 112, first paragraph for the reasons set forth above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4, 5 and 9-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation "in ~~the~~ powdered mixture" and is dependent on claim 1. There is insufficient antecedent basis for this limitation in the claim, as there is no mention of a "powdered mixture" in claim 1.

The instantly claimed process appears to be directed towards only producing the instantly claimed product; however there are differences between the two with regard to the fermenting agent. The product requires both *Saccharomyces* strain and flowers of *Woodfordia fruticosa* as fermenting agents in claim 4, but claim 9, step (g) requires *Saccharomyces* strain and a fermenting agent, implying that *Saccharomyces* strain is not a fermenting agent. Then claim 15 states that the fermenting agent used in step (g) is selected from *Saccharomyces* strain and flowers of *Woodfordia fruticosa*. This would mean that *Saccharomyces* strain could possibly be added twice in the same step. Looking to the specification for further guidance only complicates the issue as *Saccharomyces* strain is not mentioned in any of the working examples, only *Woodfordia fruticosa* is mentioned. For these reasons, claims 4, 9 and 15 are deemed vague and indefinite.

Claim 10 is vague and indefinite as it depends on itself. Therefore, claim 10 has been interpreted to depend upon claim 9, as have the subsequent claims 11-16, since this arrangement would be consistent with the typographical error that most likely occurred. Additionally claim 10 does not further limit claim 9 as the "whole plant" is included among the group of listed plant parts.

Claims 2, 5 and 11 are vague and indefinite due to the lack of saying what the given ratios are in comparison to. It is impossible to determine the metes and bounds of the claim when a ratio or percentage is specified but not described what it is in relation to. Additionally, claims 2 and 11 give a series of ratios for each herbal ingredient, but they do not add to 100%. Therefore there must be some other additional ingredients, as referred to in the specification.

As explained above in the 35 U.S.C. 112, first paragraph rejection, there is some difficulty in the interpretation of claim 9. Does the extract produced by step of 9 (c) include a decoction (boiling) step as implied by the specification or is it a simple cold infusion technique?

All other claims depend directly or indirectly from rejected claims and are therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1655

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brindavanam et al. (US 2002/0025349) in view of Himalayan Herbal Healthcare webpage and Unno (JP 58179476).

An herbal soft drink and a process for making an herbal soft drink are claimed.

As readily admitted by Applicants, the method of making of traditional beverages of India, such as medicinal drinks, alcoholic drinks and soft drinks is known to one of skill in the art (see, e.g., page 1, lines 14-15 of Applicant's specification). It is further admitted by Applicant that each of the elected species (as well as jaggery and *Woodfordia fruticosa*) is known to be an ingredient in traditional beverages called

Art Unit: 1655

arishtas in Ayurvedic texts (see, e.g., page 2, lines 3-7 and lines 20-23). Brindavanam et al. teach that arishtas, as well as asavas, are traditional medicinal wines mentioned in ancient Ayurvedic texts and are known for their accessibility, palatability and product stability (see, e.g., page 2, paragraph [0023]). Brindavanam et al. further discuss the traditional method for making arishtas and asavas (see, e.g., page 2, paragraph [0025]). In either arishtas or asavas, a coarse powder of herbal material (which would have required crushing and mixing of plant material to produce) is extracted with water (see, e.g., page 2, paragraph [0026]). For arishtas, the extraction mixture is heated, which would concentrate the mixture. As indicated by the working examples in Applicants' specification, every one of the examples is decocted (boiled), so it is most likely that Applicants' are following the procedure for making an arishta. After extraction, a filtrate is collected. Next jaggery is dissolved (mixed) in this filtrate (see, page 2, paragraph [0027]). *Woodfordia fruticosa* is then added as an inoculum bearing herb (fermenting agent) (see, e.g., page 2, paragraph [0028]). Then Brindavanam et al. teaches that the fermentation is carried out for 40-45 days, generating alcohol. This self-generated alcohol is a preservative and prolongs shelf life (see, e.g., page 2, paragraph [0033]). Brindavanam et al. does not teach the following: using the two herbs *Vitis vinifera* and *Boerhaavia diffusa*, fermenting for only 3-6 days, an explicit step of filtering the fermented mixture (although filtering the fermenting agent out of the fermented mixture, just as the extracted mixture was filtered, would be an expected step), concentrating the filtered mixture, or adding carbonated water to the concentrated mixture.

Geriforte is an herbal supplement with antioxidant action made with Ayurvedic herbs. It contains draksha (*Vitis vinifera*), punarnava (*Boerhaavia diffusa*), as well as guduchi (*Tinospora cordifolia*) and ashvagandha (*Withania somnifera*). It further contains chyavanprash concentrate, which itself contains *Vitis vinifera* and *Boerhaavia diffusa*, as well as *Sida cordifolia* and *Tinospora cordifolia*.

Unno teaches an alcoholic herbal beverage prepared using carbonated water to preserve the herbs and increase shelf life. As Applicants' period of fermentation is shorter than normal, the shelf life would also be decreased due to the lower amount of alcohol generated. To increase the shelf life on the more rapidly produced beverage, it would be obvious to add carbonated water as a preservative. Furthermore, it is well-known for one of skill in the beverage art to add carbonated water (such as tonic water) to any alcoholic beverage to produce a more palatable and refreshing product. Additionally, in order not to dilute the potency of the herbal beverage, one of ordinary skill in the art would be motivated to concentrate prior to the addition of the carbonated water.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to quickly produce an antioxidant herbal beverage similar to Geriforte using Ayurvedic herbs in an arishta made by the traditional methods, as taught by Brindavanam et al., substituting additional lengthy fermentation for the addition of carbonated water, as taught by Unno. The adjustment of particular conventional working conditions (e.g., determining the most effective ratios of ingredients and/or concentrating to the most advantageous percentage of original

Art Unit: 1655

volume) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather L. Anderson whose telephone number is (571)270-3051. The examiner can normally be reached on Monday-Thursday, 7:30 AM-5:00 PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1655

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HLA

/Christopher R. Tate/
Primary Examiner, Art Unit 1655